



## **DEPARTMENT OF COMMERCE**

### **National Institute of Standards and Technology**

#### **37 CFR Parts 401 and 404**

**[Docket No.: 230315-0076]**

**RIN 0693-AB66**

#### **Rights to Federally Funded Inventions and Licensing of Government Owned Inventions**

**AGENCY:** National Institute of Standards and Technology (NIST), United States Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** The National Institute of Standards and Technology (NIST) announces revisions to regulations in order to make several technical corrections; reorganize certain subsections; remove outdated and/or unnecessary sections; institute a reporting requirement on federal agencies; and provide clarifications on definitions, communications, process for exercising march-in rights, filing of provisional patent applications, electronic filing of Bayh-Dole related reporting, the purpose of royalties on licenses from the Federal Government, and the processes for granting exclusive, co-exclusive, and partially exclusive licenses and for appeals. NIST has not adopted in this final rule a provision in the proposed rule regarding exercising march-in rights on the sole basis of product pricing. Instead, NIST intends to engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of march-in provisions.

**DATES:** This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Bethany Loftin, via e-mail at [bethany.loftin@nist.gov](mailto:bethany.loftin@nist.gov) or by telephone at 301-975-0496.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

This final rule is promulgated under the University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at title 35 of the United States Code (U.S.C.) 200 *et seq.*, and commonly known as the “Bayh-Dole Act” or “Bayh-Dole,” and its implementing regulations, found at title 37 Code of Federal Regulations (CFR) parts 401 and 404.

The rule shall apply to all new funding agreements as defined in 37 CFR 401.2(a) that are executed after the effective date of the rule. The rule shall not apply to a funding agreement in effect on or before the effective date of the rule, provided that if such existing funding agreement is thereafter amended, the funding agency may, in its discretion, make the amended funding agreement subject to the rule prospectively.

On January 4, 2021, NIST published a notice of proposed rulemaking (NPRM) in the *Federal Register* (86 FR 35) requesting public comments on proposed revisions to the regulations at 37 CFR parts 401 and 404, as well as general comments relating to federal technology transfer practices. The NPRM described the statutory framework for the proposed rule revisions under the Bayh-Dole Act and its implementing regulations. NIST received 81,253 submissions during the public comment period, which closed on April 5, 2021, including comments, questions, suggestions, and recommendations from, *inter alia*, individual members of the public, public and private universities, professional associations, research institutions, and non-profit foundations. Of the 81,253 submissions received during the public comment period, the largest percentage of the comments related to the proposed addition to 37 CFR 401.6(e) regarding exercising march-in rights on the sole basis of product pricing. A discussion of these comments and NIST’s response is included in Comment 8 below. During the public comment period, on February 25, 2021, NIST also held a public webinar in which the proposed changes were reviewed, and public statements were accepted and made a part of the record. NIST appreciates and has considered the comments received, and this final rule reflects a number of changes to the regulations proposed in the NPRM based on this feedback.

Additionally, severability clauses have been added to both Parts 401 and 404 in this final rule. In the event that any part of the regulations is stayed or determined to be invalid, the remaining provisions should be severable and remain in effect.

### **Response to Comments**

All submissions were carefully reviewed, and NIST thanks the public for its engagement. NIST's responses to comments within the scope of this rulemaking have been correlated by topic and are summarized below.

1. *Comment:* NIST's legal authority to promulgate regulations implementing the Bayh-Dole Act was questioned by one commenter, who asserted that the regulations should instead emanate directly from the Department of Commerce.

*Response:* Authority to issue these regulations is granted to the Secretary of Commerce under 35 U.S.C. 206 and has been properly delegated to the Director of NIST under Department of Commerce Department Organization Order 30-2A.

2. *Comment:* The NPRM stated that the rulemaking was not an "economically significant" regulatory action under Executive Order 12866, "as it does not have an effect on the economy of \$100 million or more in any one year . . . ." This determination was questioned by a commenter based on the regulations' application "to all Federal agencies," and the large number of inventions and patents in which the Federal Government maintains an interest.

*Response:* NIST determined at the proposed rule stage that this rulemaking is not an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. NIST conducted an analysis, by looking at all the proposed changes and the effect of those changes on the existing regulations, and concluded that the changes to the regulations are primarily clarifications and a reorganization of existing content. NIST has compared the text of the proposed rule to the text of this final rule and affirms its earlier determination that the regulatory changes are not economically significant.

3. *Comment:* Two commenters objected to the proposed removal of § 401.1(a), which describes the effect of third-party funding on the ownership of a “subject invention” and the treatment of any invention created under a project that is closely related to, but separate from, a project funded by the Federal Government. The objecting commenters requested that these clarifications be maintained, as they are of use in determining whether or not an invention is a “subject invention.”

*Response:* NIST has re-inserted the introductory language at § 401.1(a) to maintain this additional guidance and clarification.

4. *Comment:* Multiple commenters were supportive of, objected to, and/or requested additional clarification on the proposed revisions to the newly designated § 401.6(a)(1) (previously § 401.6(b)). Those who objected or requested additional information generally expressed concern that this process would be adversarial or asked that other title holders, including exclusive licensees, also be permitted to attend the consultation.

*Response:* Both the original and the revised versions of this section establish an informal process between a funding agency and a contractor prior to the agency’s initiation of march-in procedures, though the original version limited this process to “informal written or oral comments from the contractor as well as information relevant to the matter.” The proposed language expands this process to a full informal consultation and was more explicit about the nature of the consultation, explaining that the additional factfinding would allow the agency to better “understand the nature of the issue and consider possible actions other than exercising march-in rights.” It was not the intent of this addition to create an adversarial process; the intent was to encourage informal consultation and to potentially avoid the need to proceed to formal march-in procedures. Regarding commenters’ requests to include licensees in the consultation, given its informal nature, agencies have discretion to include additional parties, if necessary. Therefore, NIST determined that explicitly including or requiring additional parties was unnecessary. To address commenters’ concerns regarding the nature of the informal consultation, NIST has replaced “actions” with “alternatives” in this final rule and added the words “may also” to the statement regarding the funding agency’s consideration of march-in alternatives.

5. *Comment:* One commenter objected to the requirement under the newly designated § 401.6(a)(1) (previously § 401.6(b)) that the contractor respond to an agency request for informal consultation within 30 days, expressing the opinion that contractors should be allowed a longer amount of time in which to respond.

*Response:* This 30-day response period was present in the previous regulations but required the contractor to provide written comments to the agency within 30 days. The revision provides this same 30-day period, but only requires the contractor to provide notice to the agency that the contractor wishes to proceed with informal consultation. Given that this revision only requires the contractor to make a determination regarding whether to participate in an informal consultation and not the time required to collect and compose comments, 30 days is a sufficient amount of time for a contractor to provide such notice, and NIST declines to lengthen the response period in this final rule.

6. *Comment:* A proposed revision to the newly designated § 401.6(a)(1) (previously § 401.6(b)) increased the amount of time for an agency to issue a decision as to whether or not it will pursue march-in rights following an informal consultation with a contractor from 60 days to 120 days. A commenter questioned the necessity of this longer response period.

*Response:* The longer period is believed appropriate to facilitate and ensure thorough agency consideration of all issues and supplementary information submitted by the contractor following informal consultation; thus, NIST has maintained the NPRM's extension from 60 days to 120 days in this final rule.

7. *Comment:* Several comments were received relating to newly designated § 401.6(a)(4) (previously § 401.6(e)), which concerns the confidentiality of information obtained during march-in proceedings. Concern was expressed over the addition of language that allows an agency to disclose information obtained during a march-in proceeding to persons outside the Federal Government when "otherwise required by law."

*Response:* The intent of this additional language is to put contractors on notice that other laws may require disclosure of the information, and compliance with such laws is mandatory, whether or not the phrase in question is added to the regulations. NIST has maintained the phrase in this final rule.

8. *Comment:* The large majority of comments received related to the new language proposed at § 401.6(e). (The NPRM redesignated the previous § 401.6(e), which relates to fact-finding during the march-in process, as the new § 401.6(a)(4)). The proposed new § 401.6(e) of the NPRM stated that “[m]arch-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.” These comments ranged in content. Many commenters stated that the provision should be removed and that the Federal Government’s right to march-in *should* be exercised solely on the basis of product pricing. Some expressed general support for the addition, and others requested additional changes to further clarify and ensure that the Federal Government would *not* march-in based on product pricing.

*Response:* The large number of comments received on this issue raise questions that warrant further consideration. Consistent with this, on July 9, 2021, the President issued Executive Order 14036 (“Promoting Competition in the American Economy”), which, *inter alia*, directed the Secretary of Commerce, acting through the Director of NIST and in light of the policies set forth in the Executive Order, to consider not finalizing “any provisions on march-in rights and product pricing” in the NPRM. Given the comments received, NIST’s examination of them, and the Executive Order, NIST removed this provision from the final rule. The circumstances in which an agency might exercise its right to march-in are enumerated in the regulations at § 401.14(j) and include (a) a contractor’s failure to take action to achieve practical application of a subsection invention, (b) a contractor’s failure to meet health or safety needs, (c) a contractor’s failure to meet public use requirements, and (d) a contractor’s failure to comply with the preference for United States industry. NIST intends to engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of

march-in provisions. In this final rule, § 401.6(e) of the NPRM is removed, and § 401.6(f) of the NPRM is redesignated as § 401.6(e).

9. *Comment:* The NPRM reorganized § 401.13, relocating certain paragraphs (e.g., § 401.13(a) became § 401.14(c)(6)), removing outdated portions, and retitling the section from “Administration of patent rights clauses” to “Confidentiality of contractor submissions.” Several commenters that were supportive of the revisions asked NIST to expand the confidentiality provisions to apply to *all* information related to “subject inventions.”

*Response:* This final rule maintains the revisions to § 401.13 that were proposed in the NPRM, which includes confidentiality protections for contractor submissions under many circumstances. While NIST appreciates the importance of maintaining the confidentiality of information related to inventions for which patent protection has not yet been sought as well as business information, NIST cannot expand confidentiality provisions beyond those provided in the Bayh-Dole statute and therefore has not expanded the confidentiality provisions in this final rule.

10. *Comment:* Several commenters objected to the proposed change in § 401.14(a)(2) amending the definition of “subject invention.” These changes included a rephrasing of the definition and the incorporation of a clarifying statement explaining that “[a]n invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention.”

*Response:* NIST has removed this revision from the final rule, as the additional guidance regarding inventions conceived without the use of any federal funds was reinstated at § 401.1(a), as discussed in Comment 3 above.

11. *Comment:* The NPRM revised § 401.14(c)(3), creating (c)(3)(i)-(iv). Several commenters expressed concern with the proposed additional language in § 401.14(c)(3)(ii) requiring that each provisional application filed after a first provisional application “contain additional written description of the subject invention not previously disclosed in a patent application.” Commenters pointed to the increasingly common practice of re-filing provisional applications since the United States moved to a

first-to-file patent system, and there was also confusion expressed as to whether prior agency approval would be needed before the filing of additional provisional patent applications.

*Response:* NIST appreciates the submitted comments and the need for contractor flexibility in developing patent filing strategy. Therefore, NIST has removed the requirement that additional written description of the subject invention be included in subsequent provisional patent filings. NIST has further revised this provision to clarify that additional provisional patent applications may be filed until the nonprovisional application is timely filed in accordance with § 401.14(c)(3)(i) and allowing for additional extensions, if needed, granted under § 401.14(c)(5). Nothing in these regulations supersedes any deadlines or requirements imposed by the United States Patent and Trademark Office.

12. *Comment:* Under § 401.14(c)(3)(iv) and if required by the funding agency, a contractor must provide information related to patent filings, including the filing date, application number, title, a copy of the patent application, patent number, and issue date. One commenter requested that this section be revised to remove the discretionary aspect, instead requiring each agency to ask for this information.

*Response:* NIST notes that many agencies already request this information as a matter of course. However, NIST leaves the collection of specific information to the discretion of funding agencies.

13. *Comment:* Several commenters supported the revision to § 401.14(d) allowing agencies to release the contractor from the requirement to convey title to a subject invention to the agency, although many commenters requested that there be a timeframe in which the agency must respond to a request for release under this provision.

*Response:* NIST will work with the interagency community to provide additional guidance on the waiver process, as needed. Because each agency concerned must adhere to different internal requirements and processes in furtherance of their unique missions, a specific time limit for agency response would not be advisable, and NIST declines to impose the same in this final rule.

14. *Comment:* At § 401.14(k), (k)(4) of the regulations was revised and divided into the newly designated sections (k)(4) and (k)(5). Both the previous regulations and the NPRM contained the requirement at § 401.14(k)(4) that the contractor make efforts that are reasonable under the



circumstances to attract licensees of subject inventions that are small business firms and, when appropriate, give preference to a small business firm when licensing a subject invention. Part of the previous § 401.14(k)(4) and the NPRM's newly designated § 401.14(k)(5) require that the contractor "negotiate changes to its licensing policies, procedures, or practices" with the funding agency if the funding agency's review of the contractor's licensing programs and decisions discloses that the contractor could take reasonable steps to more effectively implement the small business consideration requirements. Several commenters requested an amendment to the language changing "negotiate" to "consider."

*Response:* The language in question was not proposed for revision, as the requirement that small business firms be given a preference in the licensing of subject inventions is statutory, 35 U.S.C. 202. Requiring a contractor to only "consider" reasonable changes to implement this statutory requirement would be inadequate; thus, NIST has maintained the requirement that a contractor negotiate such reasonable changes with a funding agency in this final rule.

15. *Comment:* One commenter objected to the removal of § 401.15, stating that guidance on deferred determinations should be retained.

*Response:* The guidance on deferred determinations previously found at § 401.15 has been substantially retained in § 401.9 of both the proposed and final rule.

16. *Comment:* Previously entitled "Electronic filing," § 401.16 was revamped in the NPRM and retitled "Federal agency reporting requirements." Its requirements relate to information that must be reported by agencies internally, within the Federal Government. Several commenters requested the addition of language that would limit the information being reported to only that data that is already available within the iEdison system, as well as text that would require the agencies to pull the information from iEdison when fulfilling their reporting obligations so as to avoid creating an additional reporting burden for contractors.

*Response:* As noted by the commenters, many of the data points for which reporting is required under § 401.16 are currently available via iEdison, and NIST intends to incorporate the remainder in a

forthcoming update to the iEdison system to minimize the burden on agencies in fulfilling this requirement. However, while NIST appreciates the commenters' concerns and strongly supports the use of iEdison by funding agencies, NIST cannot mandate or compel agency use of iEdison, nor can NIST dictate the manner in which the agencies collect data. Accordingly, NIST declines to make the suggested revision in this final rule.

17. *Comment:* At § 404.2, entitled "Policy and objective," the NPRM amended and expanded the previous text. Comments were received objecting to the proposed revisions, observing the text's brevity as compared to the stated objectives in 35 U.S.C. 200 and questioning its consistency with the definition of "practical application."

*Response:* The text of 35 U.S.C. 200 remains governing law. The revisions at § 404.2 do not alter the definition of "practical application" found at § 401.2. The amended text does not consider payments as achieving "practical application"; it encourages the Federal Government to consider how the utilization of payments under a license agreement may encourage licensees to develop an invention in order to advance practical application and to promote commercialization by the licensee. NIST has slightly reworded § 404.2, in order to clarify the intent in this final rule.

18. *Comment:* One commenter objected to the removal of § 404.4 and requested additional language specific to certain action items, diseases, and/or products. NIST also received a comment from a federal agency to re-insert § 404.4, because the requirement to notify the public of federally owned inventions available for license is not found elsewhere within the regulation.

*Response:* The regulations are meant to apply to an invention without regard to invention type or industry sector, and therefore, NIST declines to add references to specific sectors, diseases, or products. However, although much of this section is already substantively included elsewhere, NIST agrees that the requirement to publish federally owned inventions is not. NIST will re-insert § 404.4 in its entirety keeping the language unchanged from the previous regulations.

19. *Comment:* Many commenters objected to the NPRM's proposed amendment of § 404.7(a)(1). The proposed rule retained the requirement that, prior to granting an exclusive, co-

exclusive, or partially exclusive license on a Government owned invention, the Government must first publish a notice identifying the invention on which the proposed license is to be granted. However, the proposed rule removed the requirement that the identity of the prospective licensee of a Government owned invention also be published.

*Response:* In order to keep the public apprised of prospective licensees of Government owned inventions, NIST has reincorporated the requirement that the identity of such a prospective licensee be published alongside the invention into this final rule.

20. *Comment:* One commenter objected to the NPRM's proposed rewording at § 404.7(a)(3) (previously § 404.7(a)(1)(iii)). Under the previous language, before granting an exclusive, co-exclusive, or partially exclusive license to a Government owned invention, it was required that "[t]he Federal agency ha[d] not determined that the grant of such a license [would] tend substantially to lessen competition or create or maintain a violation of the Federal antitrust laws." In the NPRM, the requirement of non-determination was altered into a requirement of affirmative determination, such that the license could be granted after "[t]he Federal agency has determined that the grant of such a license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws."

*Response:* The proposed changes in the NPRM were meant to mirror the wording in the corresponding statute at 35 U.S.C. 209(a)(4). While appreciative of the alternative language recommended, NIST only made one revision to the language proposed in the NPRM in this final rule, which moved the word "to" before the word "lessen" in order to mirror the exact wording at 35 U.S.C. 209(a)(4).

21. *Comment:* Several commenters objected to the NPRM's proposed addition of language at § 404.11(a)(3); § 404.11(a) lists the parties who may appeal certain agency decisions or determinations relating to Government owned inventions.

*Response:* Under this section, certain parties may appeal an agency decision or determination concerning the grant, denial, modification, or termination of a license, which, under § 404.5, an agency

may grant “only if the applicant has supplied the Federal agency with a satisfactory plan for development or marketing of the invention, or both, and with information about the applicant's capability to fulfill the plan.” The added language at § 404.11(a)(3) provides that a person who files a written objection to an agency’s notice of proposed licensing also demonstrate that the proposed license would deny that person the opportunity to commercialize the invention. If a third party who is not denied the opportunity to commercialize the invention opposes a proposed license, they need only find another party willing to license the invention to appeal. Requiring less would result in an appeal with the potential to result in no license or commercialization. Therefore, this additional language is maintained in the final rule.

### **Changes from the Proposed Rule**

1. Re-insert the guidance and examples in § 401.1(a).
2. Remove § 401.2(m)(4) from the definition of “patent application” and redesignate the proposed § 401.2(m)(5) as § 401.2(m)(4).
3. Remove § 401.2(n)(3) from the definition of “initial patent application,” redesignate §§ 401.2(n)(4) and (5) as §§ 401.2(n)(3) and (4) and remove “which designates the United States” from the newly designed § 401.2(n)(3).
4. Revise the first sentence of § 401.6(a)(1) to add “may also” and replace “actions” with “alternatives”.
5. Remove the proposed addition at § 401.6(e) regarding the consideration of pricing of commercial goods and services and redesignate the proposed § 401.6(f) as § 401.6(e).
6. Remove the proposed revisions to the definition of “subject invention” at § 401.14(a)(2).
7. Revise § 401.14(c)(3) by moving the last sentence of § 401.14(c)(3)(i) to § 401.14(c)(3)(ii).
8. Revise § 401.14(c)(3)(ii) to remove the requirement that additional written description be included in each provisional application filed following the initial patent application and to clarify that additional provisional applications may be filed so long as a nonprovisional is filed within the regulatory time frame, including any approved extensions.

9. Remove the proposed revision to § 401.14(f)(3).
10. Revise § 401.16 to add “(h) Summary of utilization information provided by contractors,” in accordance with the directive in Executive Order 14036 that the Secretary of Commerce, acting through the Director of NIST, consider such an addition to the regulations.
11. Add § 401.18 to include a severability clause in this Part.
12. Revise § 404.2 to clarify intent by stating that payments received under a license agreement may be considered as “a means for encouraging the licensee to develop an invention in order to advance practical application and to promote commercialization by the licensee.
13. Revise § 404.1(b) to add “and used in accordance with 15 U.S.C. 3710c(a)(1)(B),” to reiterate that royalties collected must be used in accordance with this statute.
14. Re-insert § 404.4 in its entirety.
15. Revise § 404.7(a)(1) to re-insert the phrase “and the prospective licensee” to the information required in a Notice of a prospective license.
16. Revise § 404.7(a)(3) to move the word “to” before the word “lessen” to be consistent with 35 U.S.C. 209(a)(4).
17. Add § 404.15 to include a severability clause in this Part.

#### **Executive Order 12866 and Regulatory Impact Analysis**

This rulemaking is a significant regulatory action under section 3(f)(4) of Executive Order 12866. This rulemaking, however, is not an economically significant regulatory action under section 3(f)(1) of the Executive Order, as it does not have an effect on the economy of \$100 million or more in any one year, and it does not have a material adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This rule only makes administrative changes for ease, clarity, and transparency, and therefore does not have economically significant effects.

#### **Executive Order 13132**

This rule does not contain policies with Federalism implications as defined in Executive Order 13132.

### **Regulatory Flexibility Act**

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this rule would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination was published in the proposed rule and is not repeated here. No comments were received regarding the certification, and NIST has not received any new information that would affect its determination. As a result, a final regulatory flexibility analysis was not required and none was prepared.

### **Paperwork Reduction Act**

Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information approved by OMB under the following control number: 0693-0090 - iEdison. NIST believes any overall increases/decreases in burdens and costs will be minimal and will fall within the already approved amounts for the existing collection. The public may access the current version of the collection, including all supporting materials, at [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain).

### **National Environmental Policy Act**

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

### **List of Subjects in 37 CFR Parts 401 and 404**

Inventions and patents, Laboratories, Research and development, Science and technology, Technology transfer.

For the reasons stated in the preamble, the National Institute of Standards and Technology amends 37 CFR parts 401 and 404 as follows:

**PART 401 - RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS**

1. The authority citation for 37 CFR part 401 continues to read as follows:

**Authority:** 35 U.S.C. 206; DOO 30-2A.

2. Revise § 401.1 to read as follows:

**§ 401.1 Scope.**

(a) Traditionally there have been no conditions imposed by the government on research performers while using private facilities which would preclude them from accepting research funding from other sources to expand, to aid in completing or to conduct separate investigations closely related to research activities sponsored by the government. Notwithstanding the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project, it is clear that the ownership provisions of these regulations would remain applicable in any invention “conceived or first actually reduced to practice in performance” of the project. Separate accounting for the two funds used to support the project in this case is not a determining factor.

(1) To the extent that a non-government sponsor established a project which, although closely related, falls outside the planned and committed activities of a government-funded project and does not diminish or distract from the performance of such activities, inventions made in performance of the non-government sponsored project would not be subject to the conditions of these regulations. An example of such related but separate projects would be a government sponsored project having research objectives to expand scientific understanding in a field and a closely related industry sponsored project having as its objectives the application of such new knowledge to develop usable new technology. The

time relationship in conducting the two projects and the use of new fundamental knowledge from one in the performance of the other are not important determinants since most inventions rest on a knowledge base built up by numerous independent research efforts extending over many years. Should such an invention be claimed by the performing organization to be the product of non-government sponsored research and be challenged by the sponsoring agency as being reportable to the government as a “subject invention”, the challenge is appealable as described in § 401.11(d).

(2) An invention which is made outside of the research activities of a government-funded project is not viewed as a “subject invention” since it cannot be shown to have been “conceived or first actually reduced to practice” in performance of the project. An obvious example of this is a situation where an instrument purchased with government funds is later used, without interference with or cost to the government funded project, in making an invention all expenses of which involve only non-government funds.

(b) This part implements 35 U.S.C. 202 through 204 and is applicable to any funding agreement with a nonprofit organization or small business firm as defined by 35 U.S.C. 201, except for an agreement made primarily for educational purposes under 35 U.S.C. 212. This part also applies to any funding agreement with business firms regardless of size in accordance with section 1, paragraph (b)(4) of Executive Order 12591, as amended by Executive Order 12618, unless directed otherwise pursuant to NASA or DOE vesting statutes.

(c) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations or other guidance dealing with ownership of inventions made by businesses and nonprofit organizations which are inconsistent with it. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as authorized by § 401.5 or 401.3, when alternate provisions are used under § 401.3(a)(1) through (6), are not considered deviations requiring the Secretary's approval.



(d) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered “funding agreements” as defined at 35 U.S.C. 201(b) and § 401.2(a).

3. Amend § 401.2 by revising the introductory text and paragraphs (k) through (o) to read as follows:

**§ 401.2 Definitions.**

In addition to the definitions in 35 U.S.C. 201, as used in this part—

\* \* \* \* \*

(k) The term *electronically filed* means any submission of information transmitted by an electronic system.

(l) The term *electronic system* means a software-based system approved by the agency for the transmission of information.

(m) The term *patent application* or “application for patent” may be the following:

(1) A United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or

(2) A United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or

(3) A patent application filed in a foreign country or an international patent office; or

(4) An application for a Plant Variety Protection certificate.

(n) The term *initial patent application* means, as to a given subject invention:

(1) The first United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or

(2) The first United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or

(3) The first patent application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b); or

(4) The first application for a Plant Variety Protection certificate.

(o) The term *statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

### **§ 401.3 [Amended]**

4. Amend § 401.3 as follows:

- a. Remove the words “§ 401.5(g)” and add in their place “§ 401.5(f)” in paragraph (c)(3);
- b. Remove the words “of Commerce” from the fourth sentence of paragraph (f); and
- c. Remove paragraph (g) and redesignate paragraphs (h) and (i) as paragraphs (g) and (h).

### **§ 401.4 [Amended]**

5. Amend § 401.4 as follows:

- a. Remove the words “35 U.S.C. 202(b)(4)” and add in their place “35 U.S.C. 202(b)(3)” in the first sentence of paragraph (a); and
- b. Remove the words “United States Claims Court” and add in their place “United States Court of Federal Claims” in the last sentence of paragraph (b)(6).

6. Amend § 401.5 as follows:

- a. Revise paragraphs (a) and (b);
- b. Remove paragraph (f) and redesignate paragraphs (g) and (h) as paragraphs (f) and (g);
- c. Revise newly redesignated paragraph (g).

The revisions read as follows:

### **§ 401.5 Modification and tailoring of clauses.**

(a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. If the funding agreement is a grant or cooperative agreement, paragraph (g)(3) of the clause may be deleted.

(b) Agencies should complete paragraph (l) of the clause in § 401.14, “Communication,” by designating a central point of contact for communications on matters relating to the clause. Agencies may also include additional information on communications in paragraph (l) of the clause in § 401.14.

\* \* \* \* \*

(g) If the contract is for the operation of a government-owned facility, agencies may add paragraph (f)(5) to the clause at § 401.14 with the following text:

The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the *contracting officer* so that the *contracting officer* may evaluate and determine their effectiveness.

7. Revise § 401.6 to read as follows:

**§ 401.6 Exercise of march-in rights.**

(a) The following procedures shall govern the exercise of the march-in rights of the agencies set forth in 35 U.S.C. 203 and paragraph (j) of the clause at § 401.14:

(1) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue and may also consider possible alternatives other than exercising march-in rights. In the absence of response from the contractor to the agency request for informal consultation within 30 days, the agency may, at its discretion, proceed with the procedures below. If informal consultation occurs within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 120 days after informal

consultation, either notify the contractor of the initiation of the procedures below with a summary of the efforts taken, or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

(2) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

(3) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.

(4) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In

accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee) or otherwise required by law.

(5) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.

(6) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee or exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

(7) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.

(b) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term “contractor” as used in this section shall be deemed to include the inventor.

(c) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(b).

(d) For purposes of this section the term exclusive licensee includes a partially exclusive licensee.

(e) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

**§§ 401.7 and 401.8 [Removed and Reserved]**

8. Remove and reserve §§ 401.7 and 401.8.

9. Revise § 401.9 to read as follows:

**§ 401.9 Contractor and contractor employee inventor requests for rights in inventions.**

(a) Agencies shall allow a contractor to request greater rights in an invention, including a request to return title to an invention to the contractor, when the funding agreement contains alternate provisions in accordance with § 401.3(a)(2):

(1) The agency shall consider if the circumstances which originally led the agency to invoke an exception under § 401.3(a) are currently valid and applicable to the actual subject invention.

(i) The agency shall provide the contractor the opportunity to submit information on its plans and intentions to bring the subject invention to practical application pursuant to 35 U.S.C. 200.

(ii) The agency shall assess whether government ownership of the invention will better promote the policies and objectives of 35 U.S.C. 200 than the plans and intentions submitted by the contractor.

(iii) The agency shall consider whether to allow the standard clause at § 401.14 to apply with additional conditions imposed upon the contractor's use of the invention for specific uses or applications, or with expanded government license rights in such uses or applications.

(2) The agency shall reply to the contractor with its determination within 90 days after receiving a request and any supporting information from the contractor. If a bar to patenting is sooner than 90 days from receipt of a request, the agency may either file a patent application on the subject invention or authorize the contractor to file a patent application at its own risk and expense.

(3) The Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section.

(b) Pursuant to 35 U.S.C. 202(d), a contractor is required to obtain approval from a funding Agency before assigning rights to a subject invention made under a funding agreement to an employee/inventor. When an employee/inventor retains rights to a subject invention made under a funding agreement, either the Agency or the contractor must ensure compliance by the employee/inventor with at least those conditions that would apply under paragraphs (b), (d), (f)(4), (h), (i), and (j) of the clause at § 401.14.

10. Revise § 401.11 to read as follows:

**§ 401.11 Appeals.**

(a) The agency official initially authorized to take any of the following actions shall provide the contractor with a written statement of the basis for his or her action at the time the action is taken, including any relevant facts that were relied upon in taking the action.

(1) A refusal to grant an extension under paragraph (c)(5) of the standard clause at § 401.14.

(2) A request for a conveyance of title under paragraph (d)(1) of the standard clause at § 401.14.

(3) A refusal to grant a waiver under paragraph (i) of the standard clause at § 401.14.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clause at § 401.14.

(b) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (a) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(c) Appeals procedures established under paragraph (b) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6(a)(4) through (6) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause at § 401.14, including any dispute as to whether or not an invention is a subject invention.

(d) To the extent that any of the actions described in paragraph (a) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (b) and (c) of this section.

11. Revise § 401.13 to read as follows:

**§ 401.13 Confidentiality of contractor submissions.**

Pursuant to 35 U.S.C. 202(c)(5) and 205, the following procedures shall govern confidentiality of documents submitted under paragraph (c) of the standard clause found at § 401.14:

(a) Agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention during the time which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14 or such other clause in the funding agreement. This prohibition does not apply to information that has previously been published by the inventor, contractor, or otherwise.

(b) Agencies shall not disclose or release, pursuant to requests under the Freedom of Information Act or otherwise, copies of any document which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence. This prohibition does not apply to documents published by the U.S. Patent and Trademark Office or any foreign patent office.

(c) When implementing policies that encourage public dissemination of the results of work supported by the agency through government publications or other publications of technical reports,



agencies shall not include copies of documents submitted by contractors pursuant to § 401.14(c) when a contractor notifies the agency that a particular report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, or such publication could create a statutory bar to obtaining patent protection.

12. In § 401.14, amend the clause by:

- a. Revising paragraphs (a)(7) and (8); and (c)(1) and (3);
- b. Adding paragraph (c)(6);
- c. Revising paragraph (d);
- d. Removing the word “sucessor” and adding in its place “successor” in the final sentence of paragraph (e)(1);
- e. Removing the word “incidental” and adding in its place “incidental” in paragraph (k)(3);
- f. Revise paragraph (k)(4);
- g. Add paragraphs (k)(5) and (6);
- h. Add paragraph (m).

The revisions read as follows:

**§ 401.14 Standard patent rights clauses.**

\* \* \* \* \*

(a) \* \* \*

(7) *Statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

(8) *Contractor* means any person, small business firm, or nonprofit organization, or, as set forth in section 1, paragraph (b)(4) of Executive Order 12591, as amended, any business firm regardless of size, which is a party to a funding agreement.

\* \* \* \* \*

(c) \* \* \*

(1) The *contractor* will disclose each subject invention to the *Federal agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the *contract* under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention, and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the *agency*, the *contractor* will promptly notify the *agency* of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the *contractor*. If required by the *Federal agency*, the *contractor* will provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report, and will provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

\* \* \* \* \*

(3)(i) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use.

(ii) If the *contractor* files a provisional application as its initial patent application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. So long as there is a pending patent application for the subject invention and the statutory period wherein valid patent protection can be obtained in the United States has not expired, additional provisional applications may be filed within the initial 10 months or any extension period granted under paragraph (c)(5) of this clause. If an extension(s) is granted under paragraph (c)(5) of this clause, the *contractor* shall file a

nonprovisional patent application prior to the expiration of the extension(s) or notify the agency of any decision not to file a nonprovisional application prior to the expiration of the extension(s), or if earlier, 60 days prior to the end of any statutory period wherein valid patent protection can be obtained in the United States.

(iii) The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(iv) If required by the *Federal agency*, the *contractor* will provide the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the *contractor* has applied for a patent.

\* \* \* \* \*

(6) In the event a subject invention is made under funding agreements of more than one agency, at the request of the *contractor* or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(d) Conditions When the Government May Obtain Title

(1) A *Federal agency* may require the *contractor* to convey title to the *Federal agency* of any subject invention—

(i) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title.

(ii) In those countries in which the *contractor* fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the *contractor* has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the *Federal agency*, the *contractor* shall continue to retain title in that country.

(iii) In any country in which the *contractor* decides not to continue the prosecution of any nonprovisional patent application for, to pay a maintenance, annuity or renewal fee on, or to defend in a reexamination or opposition proceeding on, a patent on a subject invention.

(2) A *Federal agency*, at its discretion, may waive the requirement for the *contractor* to convey title to any subject invention.

\* \* \* \* \*

(k) \* \* \*

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that, when appropriate, it will give a preference to a small business firm when licensing a subject invention;

(5) The *Federal agency* may review the *contractor's* licensing program and decisions regarding small business applicants, and the *contractor* will negotiate changes to its licensing policies, procedures, or practices with the *Federal agency* when the *Federal agency's* review discloses that the *contractor* could take reasonable steps to more effectively implement the requirements of paragraph (k)(4) of this clause; and

(6) The *Federal agency* may take into consideration concerns presented by small businesses in making such determinations in paragraph (k)(5) of this clause.

\* \* \* \* \*

(m) Electronic Filing

(1) Unless otherwise requested or directed by the *Federal agency*--

(i) The written disclosure required in (c)(1) of this clause shall be electronically filed;

(ii) The written election required in (c)(2) of this clause shall be electronically filed; and

(iii) If required by the agency to be submitted, the close-out report in paragraph (c)(1) of this clause and the patent information and periodic reporting identified in paragraph (c)(3) of this clause shall be electronically filed.

(2) Other written notices required in this clause may be electronically delivered to the agency or the *contractor* through an electronic database used for reporting subject inventions, patents, and utilization reports to the funding agency.

**§ 401.15 [Removed and Reserved]**

13. Remove and reserve § 401.15.

14. Revise § 401.16 to read as follows:

**§ 401.16 Federal agency reporting requirements.**

Federal agencies will report annually to the Secretary on data pertaining to reported subject inventions under a funding agreement, including—

- (a) Number of subject inventions reported to the Federal agency;
- (b) Patent applications filed on subject inventions;
- (c) Issued patents on subject inventions;
- (d) Number of requests and number of requests granted for extension of the time for disclosures, election, and filing per 37 CFR 401.14(c)(5);
- (e) Number of subject inventions conveyed to the Government in accordance with 37 CFR 401.14(d);
- (f) Number of waivers requested and waivers granted per 37 CFR 401.14(i);
- (g) Number of requests for assignment of invention rights; and
- (h) Summary of utilization information provided by contractors.

Such information will be received by the Secretary no later than the last day of October of each year.

**§ 401.17 [Amended]**

15. Amend § 401.17 by removing the phrase “, telephone (301) 435-1986”.

16. Add § 401.18 to read as follows:

**§ 401.18 Severability.**

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in effect.

## **PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS**

17. The authority citation for 37 CFR part 404 continues to read as follows:

**Authority:** 35 U.S.C. 207-209, DOO 30-2A.

18. Revise § 404.1 to read as follows:

### **§ 404.1 Scope of part.**

(a) This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed.

This part does not affect licenses which:

(1) Were in effect prior to April 7, 2006;

(2) May exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts;

(3) Are the result of an authorized exchange of rights in the settlement of patent disputes, including interferences; or

(4) Are otherwise authorized by law or treaty, including 35 U.S.C. 202(e), 35 U.S.C. 207(a)(3) and 15 U.S.C. 3710a, which also may authorize the assignment of inventions. Although licenses on inventions made under a cooperative research and development agreement (CRADA) are not subject to this regulation, agencies are encouraged to apply the same policies and use similar terms when appropriate. Similarly, this should be done for licenses granted under inventions where the agency has acquired rights pursuant to 35 U.S.C. 207(a)(3).

(b) Royalties collected pursuant to this part, and used in accordance with 15 U.S.C. 3710c(a)(1)(B), are not intended as an alternative to appropriated funding or as an alternative funding mechanism.

19. Revise § 404.2 to read as follows:

**§ 404.2 Policy and objective.**

It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process. In negotiating licenses, the Government may consider payments under a licensing agreement as a means for encouraging the licensee to develop an invention in order to advance practical application and promote commercialization by the licensee.

**§ 404.5 [Amended]**

20. Amend § 404.5 by removing the words “§ 404.5(a)(2)” from paragraph (b)(8)(iv) and adding in their place “35 U.S.C. 209(b).”

21. Revise § 404.7 to read as follows:

**§ 404.7 Exclusive, co-exclusive, and partially exclusive licenses.**

(a) Exclusive, co-exclusive or partially exclusive licenses may be granted on Government owned inventions, only if:

(1) Notice of a prospective license identifying the invention and the prospective licensee has been published and responses, if any, reviewed in accordance with 35 U.S.C. 209(e). The agency, in its discretion, may include other information as appropriate;

(2) After expiration of the public notice period and consideration of any written objections received in accordance with 35 U.S.C. 209(e), the Federal agency has determined that:

(i) The public will be served by the granting of the license, as indicated by the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public;

(ii) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public; and

(iii) Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public;

(3) The Federal agency has determined that the grant of such a license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws;

(4) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capability of the firms and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time; and

(5) In the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) In addition to the provisions of § 404.5, the following terms and conditions apply to exclusive, co-exclusive and partially exclusive licenses:

(1) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice or have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

(2) The license shall reserve to the Federal agency the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety needs.

(3) The license shall be subject to any licenses in force at the time of the grant of the exclusive, co-exclusive or partially exclusive license.

(4) The license may grant the licensee the right to take any suitable and necessary actions to protect the licensed property, on behalf of the Federal Government.

(c) Federal agencies shall maintain a record of determinations to grant exclusive, co-exclusive or partially exclusive licenses.



**§ 404.10 [Amended]**

22. Amend § 404.10 by removing the words “and any sublicensee of record”.

23. Amend § 404.11 by revising paragraph (a) introductory text and paragraphs (a)(3) and (b) to read as follows:

**§ 404.11 Appeals.**

(a) The following parties may appeal to the agency head or designee of the Federal agency any decision or determination concerning the grant, denial, modification, or termination of a license:

\* \* \* \* \*

(3) A person who timely filed a written objection in response to the notice required by § 404.7 and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action due to being denied the opportunity to promote the commercialization of the invention.

(b) The Federal agency shall establish appropriate procedures for considering appeals under paragraph (a) of this section.

24. Revise § 404.14 to read as follows:

**§ 404.14 Confidentiality of information.**

35 U.S.C. 209(f) requires that any plan submitted pursuant to § 404.8(a)(8) and any report required by 35 U.S.C. 209(d)(2) shall be treated as commercial or financial information obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. 552.

25. Add § 404.15 to read as follows:

**§ 404.15 Severability.**

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall remain in effect.